

Notice of Allowability

Application No.

09/996,555

Applicant(s)

DITTMAR ET AL.

Examiner

Art Unit

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed 11/05/04.
2. ☒ The allowed claim(s) is/are 1-11 and 14-37 (claims are renumbered).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

Examiner acknowledges receipt amendment and remarks filed 11/05/04. Claims 1-11 and 14- 37 are pending.

Allowable Subject Matter

1. The following is an examiner's statement of reasons for allowance:

Iamartino et al. (US 5,171,580 cited by applicants in Form PTO 1449) discloses an oral pharmaceutical preparation that comprises a core of active ingredient coated with three protective layers, an inner coating layer that comprises EUDRAGIT S (column 3, lines 21-23 and 36-57 and EUDRAGIT S is the case where the carboxyl group to the ester group is 1:2), an intermediate gelling polymer layer that comprises cellulose derivatives (column 3, lines 24-26 and 58-68), and an outer layer of gastro-resistant polymer that comprises enteric material selected from cellulose acetate phthalate, hydroxypropylmethyl cellulose phthalate, polyvinyl acetate phthalate, hydroxyethyl cellulose phthalate, cellulose acetate tetrahydrophthalate and EUDRAGIT L that dissolves at pH 5.5 (column 3, lines 28-30; column 4, lines 21-29). The difference between Iamartino and the instant claims is that Iamartino requires an intermediate gelling polymer layer between the inner and outer layers whereas the instant claims consists essentially of inner and outer layers.

Rommelmayer (WO 98/27967, provided by applicants in Form PTO 1449) discloses a compressed tablet formulation that comprises a core of active ingredients and excipients, an enteric inner coating layer of EUDRAGIT L 30D or phthalate and an outer coating layer of EUDRAGIT RL or mixture of EUDRAGIT RS and EUDRAGIT RL (page 1, lines 3-21; page 8, lines 31 and 32; example 1; page 11, lines 4-14, 29 and 30; page 14, lines 17 and 18-33). The

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lines 31 and 32; example 1; page 11, lines 4-14, 29 and 30; page 14, lines 17 and 18-33). The outer coating of Rommelmayer differs from the outer coating required by instant claims.

Shah et al. (US 5,482,718) discloses a drug delivery system that comprises a drug core, an erodible polymer layer surrounding the core and the erodible polymer layer is cellulose ether derivatives or mixture of cellulose ether derivative with microcrystalline cellulose, and an outer enteric coating of methacrylic acid/methyl methacrylate copolymer in which the carboxyl group to the ester group is 1:1, EUDRAGIT L100 (column 2, lines 1-46 and lines 62-66; column 3, lines 14-52). The inner erodible polymer layer of Shah differs from the inner coating layer of the instant claims.

The pending claims are thus allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

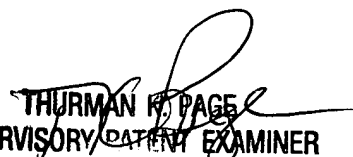
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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